

documents Apotex was moving to compel, or a protective order governing the use of those documents, but never did. Instead, Pfizer filed a protective order motion *over two weeks after this Court ordered* Pfizer to produce settlement agreements it entered into with previous atorvastatin ANDA-filers and documents relating to generic entry of atorvastatin, *Pfizer*, 2010 WL 3087458, at *9, and within four business days of the Court-ordered deadline for such production (August 25, 2010), *id.* So Pfizer's protective order motion was clearly dilatory. Moreover, we have now learned that Pfizer never truly complied with the Court's August 4 Order. But Pfizer never addresses this in its opposition to the instant motion, instead relying on language taken out of context from the oral argument on Pfizer's protective order motion to suggest that the Court has had second thoughts on its unqualified production order issued on August 4—an entirely nonsensical suggestion when the entirety of the transcript from the September 13 oral argument on Pfizer's protective order motion is carefully reviewed.

2. **Second**, Pfizer asserts that the instant Motion is “entirely premature,” arguing that during the September 13 oral argument “the Court indicated that part of the relief granted to Pfizer may be to allow redactions to the documents at issue,” and quoting out of context from the following portion of the September 13 oral argument transcript in support of its theory:

THE COURT: What about the generic documents?

MR. ALUL: Your Honor, the entire purpose --

THE COURT: Some of them have all kinds of stuff about future plans.

MR. ALUL: That's correct, your Honor, but we would submit, your Honor, that that information is irrelevant to Apotex and Pfizer has not shown anything otherwise. Apotex's only concern, your Honor, is getting out on to the market with its product. The information that stands between Apotex and doing that is publicly known. It's Pfizer's patents in this case and the Hatch-Waxman legislation, and Pfizer's settlement agreement, we would submit its anti-competitive settlement agreement with the first Atorvastatin ANDA filer, Ranbaxy. That's the only thing that's blocking entry of Apotex's generic product. We know that. All the other stuff in the market entry documents is irrelevant to

Apotex. We are just concerned with getting our product out on the market as quickly as possible. That's the way this stuff works.

THE COURT: Suppose I have them redact everything other than that?

(D.I. 222, Pfizer's Resp. at 3 (quoting Sept. 13, 2010 Tr. of Proceedings before the Hon. Martin C. Ashman ("Sept. 13 Tr.") at 5-6 (attached at D.I. 222-4, Pfizer's Resp. Ex. D))). But Pfizer quotes the Court entirely out of context in an attempt to muddle an otherwise clear issue. To begin with, the redactions complained of in the instant motion are redactions made by Pfizer in the settlement agreements, not the generic entry documents, which is what the quoted dialogue between the Court and counsel for Apotex concerned. The Court has never given any indication that Pfizer might be allowed to redact material from the settlement agreements; to the contrary, the Court indicated that it never contemplated such leave being given to Pfizer. (See D.I. 222-4, Pfizer's Resp. Ex. D, Sept. 13 Tr. 9:19 ("THE COURT: I don't remember any such [leave being given to Pfizer to redact the documents ordered to be produced]")).

Indeed, to the best of Apotex's knowledge, Pfizer has not made any redactions in the generic entry documents other than redactions for privilege. That the Court contemplated allowing Pfizer to redact information from the generic entry documents at the September 13 oral argument says absolutely nothing about the propriety of Pfizer's actions with respect to the principle complained of conduct here: Pfizer's decision to redact information—dollar amounts—*from the settlement agreements* it was ordered to produce because Pfizer unilaterally deemed that information irrelevant.

Pfizer then argues that Apotex's demand for enforcement and sanctions is premature because Apotex "hasn't even reviewed the documents in question." (D.I. 222, Pfizer's Resp. at 4). But this suggestion ducks the entire issue raised by the instant Motion—why did Pfizer think it could redact anything, let alone dollar amounts, from the settlement agreements it was ordered

to produce on August 4 when the Court's August 4 Order was clear, unequivocal, and did not grant Pfizer leave to redact any information it unilaterally deemed was irrelevant? The cat is out of the bag—Pfizer has redacted dollar amounts from the settlement agreements when it never had leave to do so from the Court, in violation of this Court's August 4 Order. Pfizer completely dodges this issue.

3. **Third**, Pfizer's opposition to the instant motion exposes Pfizer's true motivation behind its dilatory protective order motion (D.I. 192) and its intentional violation of this Court's August 4 order—Pfizer is trying to get a second crack at its opposition to Apotex's Motion to Compel (D.I. 146). Specifically, Pfizer—under the cover of its protective order motion and its opposition to the instant motion—is attempting to reargue the relevancy of information contained in the settlement agreements and generic entry documents this Court ordered produced on August 4. Pfizer wildly asserts that “Apotex does not dispute the information redacted is irrelevant to the causes of action or defenses in this case,” quoting entirely out of context from the following portion of the September 13 oral argument:

THE COURT: Some of them have all kinds of stuff about future plans.

MR. ALUL: That's correct, your Honor, but we would submit, your Honor, that that information is irrelevant to Apotex and Pfizer has not shown anything otherwise

(D.I. 222-4, Pfizer's Resp. Ex. D, Sept. 13 Tr. 5:24 – 6:3).

To begin with, Pfizer should not be allowed to reargue its opposition to a motion—Apotex's Motion to Compel (D.I. 146)—all over again. This Court should reject Pfizer's relevancy arguments, as the Court has already decided that the documents ordered to be produced are relevant to obviousness, patent misuse, and irreparable harm. *Pfizer*, 2010 WL 3087458, at *3-4. But, even if the Court were to entertain Pfizer's relevancy rearguments, the above-quoted language from the September 13 oral argument pertained only to the generic entry

documents and did not whatsoever deal with the settlement agreements Pfizer was ordered to produce and Pfizer's redactions to those agreements. Apotex has always maintained that nothing in the settlement agreements should be redacted because everything in those agreements—including dollar amounts—is non-privileged and relevant to Apotex's obviousness defenses.¹

With respect to the generic entry documents, while the Court raised some concern about "future plans" contained within the generic entry documents (see above-quoted language), counsel for Apotex responded that *the entirety* of the generic entry documents, including information about future plans, was relevant to irreparable harm and should therefore *not be redacted*:

THE COURT: Suppose I have them redact everything other than that?

MR. ALUL: If the court believes that that is the best way to go, then fine, but your Honor ordered those documents produced because they are relevant to irreparable harm. Pfizer is seeking a permanent injunction with respect to irreparable harm.

The documents and the information contained therein *even about stuff that talks about future stuff* would be relevant to the irreparable harm inquiry. Pfizer in connection with its motion, with the relief it's seeking as far as a permanent injunction is going to have to prove that if Apotex were to jump into the market, it would be irreparably harmed.

These documents speak to exactly what Pfizer's anticipated reaction upon generic entry are going to be

(D.I. 222-4, Pfizer Resp. Ex. D, Sept. 13 Tr. 6:17 – 7:4 (emphasis added)). Thereafter, as counsel for Apotex pointed out that the generic entry documents were relevant to Apotex, because Apotex's only concern is getting to the market as soon as possible:

¹ Indeed, with respect to the dollar amounts Pfizer redacted from the settlement agreements—the complained of conduct with respect to the instant Motion—such information is entirely relevant to the issue of commercial success in this case, on which this Court already ordered the settlement agreements produced. *Pfizer*, 2010 WL 3087458, at *3-4. Specifically, if previous atorvastatin ANDA-filers settled for trivial amounts of money, that would show that those ANDA-filers had little concern for three of the patents currently asserted by Pfizer in this suit—U.S. Patent Nos. 5,273,995, 40,667 E, and 5,969,156—thus supporting Apotex's arguments of obviousness and no commercial success for Lipitor[®] tied to those patents. *See id.* at *3-4.

MR. ALUL: Your Honor, there is no inconsistency here. We need the information in the market entry documents so we can assess whether or not Pfizer can establish whether or not it will be irreparably harmed if Apotex enters the market. The information in those documents is useless to Apotex thereafter.

(D.I. 222-4, Pfizer Resp. Ex. D, Sept. 13 Tr. 9:3-7). Thus, Apotex was taking issue with Pfizer assertion that “the additional information [in the generic entry documents] is highly relevant to a myriad of other highly sensitive commercial issues” (D.I. 222, Pfizer Resp. at 5), not arguing that certain information in the generic entry documents was somehow irrelevant to the very reason why the Court ordered the generic entry documents produced (irreparable harm). Pfizer’s disingenuous attempts to mislead the Court should be rejected.

4. ***Fourth***, Pfizer’s shameless attempts to mislead the Court in its opposition to the instant motion highlight Pfizer’s bad faith motive in intentionally violating this Court’s August 4 Order. Pfizer never once had any legitimate justification for redacting information it unilaterally deemed irrelevant from the settlement agreements it produced on August 25, 2010, and Pfizer’s opposition to the instant motion utterly fails to propound a good faith explanation as to why, on August 25, it felt at liberty to redact information from settlement agreements this Court ordered produced in their entirety on August 4.

* * *

For the foregoing reasons and the reasons explained in Apotex’s Motion for Enforcement of this Court’s August 4, 2010 Order for Sanctions for Plaintiff Pfizer’s Violation of Same (D.I. 219), this Court should enforce its August 4 Order and compel Pfizer once and for all to produce the settlement agreements and generic entry documents without redactions for relevancy. Moreover, Pfizer should be sanctioned for its gamesmanship and blatant disregard for this Court’s authority.

Dated: September 20, 2010.

Respectfully submitted,

APOTEX INC. AND APOTEX CORP.

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CERTIFICATE OF SERVICE

I, Andrew M. Alul, an attorney, hereby certify that on this 20th day of September, 2010, a true and correct copy of the foregoing DEFENDANT APOTEX'S REPLY IN SUPPORT OF ITS MOTION FOR ENFORCEMENT OF THIS COURT'S AUGUST 4, 2010 ORDER AND SANCTIONS FOR PLAINTIFF PFIZER'S VIOLATION OF SAME was filed with the Clerk of the Court using the Electronic Case Filing (ECF) system which will send notification of such filing via electronic mail to all counsel of record.

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